

Pt. 1305

21 CFR Ch. II (4–1–01 Edition)

- (B) Diethylpropion (Amfepramone);
- (C) Ethchlorvynol;
- (D) Ethinamate;
- (E) Lefetamine (SPA);
- (F) Mazindol;
- (G) Meprobamate;
- (H) Methylphenobarbital;
- (I) Phenobarbital;
- (J) Phentermine; and
- (K) Pipradrol.

(2) Data shall be presented in such a manner as to identify the particular form, strength, and trade name, if any, of the product containing the controlled substance for which the report is being made. For this purpose, persons filing reports shall utilize the National Drug Code Number assigned to the product under the National Drug Code System of the Food and Drug Administration.

(e) *Transactions reported.* Acquisition/distribution transaction reports shall provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies). Manufacturing reports shall provide data on material manufactured, manufacture from other material, use in manufacturing other material and use in producing dosage forms.

(f) *Exceptions.* A registered institutional practitioner who repackages or relabels exclusively for distribution or who distributes exclusively to (for dispensing by) agents, employees, or affiliated institutional practitioners of the registrant may be exempted from filing reports under this section by applying to the ARCOS Unit of the Administration.

(Approved by the Office of Management and Budget under control number 1117–0003)

[62 FR 13962, Mar. 24, 1997]

PART 1305—ORDER FORMS

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AUTHORITY: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

SOURCE: 36 FR 7796, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

§ 1305.01 Scope of part 1305.

Procedures governing the issuance, use, and preservation of order forms pursuant to section 1308 of the Act (21 U.S.C. 828) are set forth generally by that section and specifically by the sections of this part.

§ 1305.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13963, Mar. 24, 1997]

§ 1305.03 Distributions requiring order forms.

An order form (DEA Form 222) is required for each distribution of a Schedule I or II controlled substance except to persons exempted from registration under part 1301 of this chapter; which are exported from the United States in conformity with the Act; or for delivery to a registered analytical laboratory, or its agent approved by DEA.

[62 FR 13963, Mar. 24, 1997]

§ 1305.04 Persons entitled to obtain and execute order forms.

(a) Order forms may be obtained only by persons who are registered under section 303 of the Act (21 U.S.C. 823) to handle controlled substances listed in Schedules I and II, and by persons who are registered under section 1008 of the Act (21 U.S.C. 958) to export such substances. Persons not registered to handle controlled substances listed in

Schedule I or II and persons registered only to import controlled substances listed in any schedule are not entitled to obtain order forms.

(b) An order form may be executed only on behalf of the registrant named thereon and only if his/her registration as to the substances being purchased has not expired or been revoked or suspended.

[36 FR 7796, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13964, Mar. 24, 1997]

§ 1305.05 Procedure for obtaining order forms.

(a) Order Forms are issued in mailing envelopes containing either seven or fourteen forms, each form containing an original duplicate and triplicate copy (respectively, Copy 1, Copy 2, and Copy 3). A limit, which is based on the business activity of the registrant, will be imposed on the number of order forms which will be furnished on any requisition unless additional forms are specifically requested and a reasonable need for such additional forms is shown.

(b) Any person applying for a registration which would entitle him/her to obtain order forms may requisition such forms by so indicating on the application form; order forms will be supplied upon the registration of the applicant. Any person holding a registration entitling him/her to obtain order forms may requisition such forms for the first time by contacting any Division Office or the Registration Unit of the Administration. Any person already holding order forms may requisition additional forms on DEA Form 222a which is mailed to a registrant approximately 30 days after each shipment of order forms to that registrant or by contacting any Division Office or the Registration Unit of the Administration. All requisition forms (DEA Form 222a) shall be submitted to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005.

(c) Each requisition shall show the name, address, and registration number of the registrant and the number of books of order forms desired. Each requisition shall be signed and dated by

the same person who signed the most recent application for registration or for reregistration, or by any person authorized to obtain and execute order forms by a power of attorney pursuant to § 1305.07.

(d) Order forms will be serially numbered and issued with the name, address and registration number of the registrant, the authorized activity and schedules of the registrant. This information cannot be altered or changed by the registrant; any errors must be corrected by the Registration Unit of the Administration by returning the forms with notification of the error.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5319, Feb. 13, 1986; 53 FR 4963, Feb. 19, 1988; 62 FR 13964, Mar. 24, 1997]

§ 1305.06 Procedure for executing order forms.

(a) Order forms shall be prepared and executed by the purchaser simultaneously in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222. Order forms shall be prepared by use of a typewriter, pen, or indelible pencil.

(b) Only one item shall be entered on each numbered line. An item shall consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance. The number of lines completed shall be noted on that form at the bottom of the form, in the space provided. Order forms for carfentanil, etorphine hydrochloride, and diprenorphine shall contain only these substances.

(c) The name and address of the supplier from whom the controlled substances are being ordered shall be entered on the form. Only one supplier may be listed on any form.

(d) Each order form shall be signed and dated by a person authorized to sign an application for registration. The name of the purchaser, if different from the individual signing the order form, shall also be inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location